4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3037]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Quantitative Testing for the Development of Food and Drug Administration Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0865. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for Quantitative Testing for the Development of FDA Communications

OMB Control Number 0910-0865--Extension

This notice requests extension of OMB approval of the FDA information collection for a generic clearance that allows FDA to use quantitative social/behavioral science data collection techniques (i.e., surveys and experimental studies) to test consumers' reactions to FDA communications or educational messaging about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. To ensure that communications activities and educational campaigns have the highest potential to be received, understood, and accepted by those for whom they are intended, it is important to assess communications while they are under development. Understanding consumers' attitudes, motivations, and behaviors in response to potential communications and education messaging plays an important role in improving FDA's communications.

If the following conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process:

- The collections are voluntary;
- The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;
- The collections are noncontroversial;
- Personally identifiable information (PII) is collected only to the extent necessary[1] and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;[2] and

[1] For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All Privacy Act requirements will be met.

[2] As defined in OMB and Agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

- Information gathered will yield qualitative findings; the collections will not be designed or expected to yield statistical data or used as though the results are generalizable to the population of study.

To obtain approval for an individual generic collection submission that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (e.g., a copy of the survey or experimental design and stimuli for testing).

FDA will submit individual quantitative collections under this generic clearance to OMB. Individual quantitative collections will also undergo review by FDA's Research Involving Human Subjects Committee, senior leadership in the Center for Food Safety and Applied Nutrition, and PRA specialists.

Respondents to this collection of information may include a wide range of consumers and other FDA stakeholders, such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

In the *Federal Register* of September 9, 2021 (86 FR 50544), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and, therefore, will not be discussed in this document.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden by Anticipated Data Collection Methods[1]

Survey Type	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Response	Total Hours
Cognitive Interviews Screener	720	1	720	0.083 (5 minutes)	60
Cognitive Interviews	144	1	144	1	144
Pre-test Study Screener	2,400	1	2,400	0.083 (5 minutes)	199
Pre-test Study	480	1	480	0.25 (15 minutes)	120
Self-administered Surveys/Experimental Studies Screener	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-administered Surveys/Experimental Studies	15,000	1	15,000	0.25 (15 minutes)	3,750

Survey Type	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Response	Total Hours
Total					10,498

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. The total estimated annual burden is 10,498 hours. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: January 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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